Richardson et al., Application No. 10/627,439

Examiner: Rae, Charlesworth; Art Unit: 1614

Amendment No. 2; Reply to Office Action of March 14, 2007

### Amendments to the Claims:

The following is a complete list of claims indicating the changes incorporated by the present amendment and replacing all prior versions of the claims. Any claims canceled herein and all deletions made in claims that are not canceled herein are done so without prejudice to being re-instituted at a later date in this or a related application.

# **Listing of Claims:**

#### Claims 1-28 (canceled)

- 1 Claim 29 (currently amended): A layered oral dosage tablet for the treatment of herpes
- 2 simplex and conditions giving rise thereto, said layered tablet comprising an immediate-release
- 3 layer and a sustained-release layer, and comprising the following as active ingredients distributed
- 4 between said immediate-release layer and said sustained-release layer in the following
- 5 approximate proportions expressed as relative weight percents:

•	Immediate-Release Layer	Sustained-Release Layer
Magnesium L-ascorbate	40-60%	balance
2-Amino-2-deoxy-D-glucose	40-60%	balance
L-lysine monohydrochloride	40-60%	balance
N-acetyl-L-cysteine	40-60%	balance
Quercetin	40-60%	balance
L-Selenomethionine	100%	
Copper sulfate	100%	
Zinc picolinate	40-60%	balance

- 1 Claim 30 (currently amended): A layered oral dosage tablet for use as an oral dosage form,
- 2 said layered tablet comprising an immediate-release layer and a sustained-release layer, and
- 3 comprising the following as active ingredients distributed between said immediate-release layer

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4 and said sustained-release layer in the following approximate proportions expressed as relative

#### 5 weight percents:

	Immediate-Release Layer	Sustained-Release Layer
Magnesium taurate	40-60%	balance
L-selenomethionine	100%	
2-Amino-2-deoxy-D-glucose	40-60%	balance
L-Lysine ascorbate	50-60%	balance
Copper sulfate	100%	
Zinc lysinate	40-60%	balance
N-acetyl-L-cysteine	40-60%	balance
Quercetin	40-60%	balance

## Claims 31-48 (canceled)

- 1 Claim 49 (withdrawn): A unit dosage form for the treatment of herpes simplex and conditions
- 2 giving rise thereto, said unit dosage form being a vaginal dosage form selected from the group
- 3 consisting of vaginally appropriate suppositories, creams, tablets and gels, comprising as active
- 4 ingredients:

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- (a) about 1.3  $\mu$ g/mL to about 30  $\mu$ g/mL of ascorbic acid,
- 6 (b) about 0.01 mg/mL to about 0.2 mg/mL of 2-amino-2-deoxy-D-glucose,
- 7 (c) about  $0.06 \mu g/mL$  to about  $8.5 \mu g/mL$  of zinc sulfate, and
- 8 (d) about 1.6  $\mu$ g/mL to about 23  $\mu$ g/mL of L-lysine hydrochloride.
- 1 Claim 50 (withdrawn): A unit dosage form in accordance with claim 49 further comprising as
- 2 an active ingredient copper sulfate in a concentration ranging from about 0.4  $\mu$ g/mL to about 15
- 3  $\mu$ g/mL.
- 1 Claim 51 (withdrawn): A unit dosage form in accordance with claim 49 further comprising as
- 2 an active ingredient quercetin in a concentration ranging from about 0.12 μg/mL to about 2.75
- 3  $\mu$ g/mL.

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Claim 52 (withdrawn): A unit dosage form in accordance with claim 49 further comprising as 1 an active ingredient heparin sodium in a concentration ranging from about 0.6 unit/mL to about 8 2 3 units/mL. Claim 53 (withdrawn): A unit dosage form in accordance with claim 49 further comprising as 1. an active ingredient quercetin in a concentration ranging from about 0.12  $\mu$ g/mL to about 2.75 2 3 μg/mL and heparin sodium in a concentration ranging from about 0.6 unit/mL to about 8 units/mL. 4 1 Claim 54 (withdrawn): A unit dosage form in accordance with claim 49 further comprising as 2 an active ingredient quercetin in a concentration ranging from about 0.12  $\mu$ g/mL to about 2.75 μg/mL, heparin sodium in a concentration ranging from about 0.6 unit/mL to about 8 units/mL, 3 and N-acetylcysteine in a concentration ranging from about 0.6 units/mL to about 8 units/mL. 4 Claim 55 (withdrawn): A unit dosage form for the treatment of herpes simplex and conditions 1 giving rise thereto, said unit dosage form being a mucosal dosage form selected from the group 2 3 consisting of vaginally appropriate suppositories, creams, tablets and gels, comprising as active 4 ingredients: 5 (a) ascorbic acid, (b) 2-amino-2-deoxy-D-glucose, 6 (c) zinc sulfate, and 7 8 (d) L-lysine hydrochloride. Claim 56 (withdrawn): A unit dosage form in accordance with claim 55 in which the 1 2 concentrations of said active ingredients are as follows: 3 (a) about 1.3  $\mu$ g/mL to about 30  $\mu$ g/mL of ascorbic acid, (b) about 0.01 mg/mL to about 0.2 mg/mL of 2-amino-2-deoxy-D-glucose, 4 5 (c) about 0.06  $\mu$ g/mL to about 8.5  $\mu$ g/mL of zinc sulfate, and 6 (d) about 1.6  $\mu$ g/mL to about 23  $\mu$ g/mL of L-lysine hydrochloride.

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- 1 Claim 57 (withdrawn): A unit dosage form in accordance with claim 55 further comprising as
- 2 an active ingredient copper sulfate in a concentration ranging from about 0.4  $\mu$ g/mL to about 15
- 3  $\mu$ g/mL.
- 1 Claim 58 (withdrawn): A unit dosage form in accordance with claim 55 further comprising as
- 2 an active ingredient heparin sodium in a concentration ranging from about 0.6 units/mL to about
- 3 8 units/mL.
- 1 Claim 59 (withdrawn): A unit dosage form in accordance with claim 55 further comprising as
- 2 active ingredients copper sulfate in a concentration ranging from about 0.4  $\mu$ g/mL to about 15
- 3 μg/mL and heparin sodium in a concentration ranging from about 0.6 units/mL to about 8
- 4 units/mL.
- 1 Claim 60 (withdrawn): A unit dosage form in accordance with claim 55 further comprising as
- an active ingredient N-acetyl-L-cysteine in a concentration ranging from about 0.02 mg/mL to
- 3 about 0.5 mg/mL.
- 1 Claim 61 (withdrawn): A unit dosage form in accordance with claim 55 further comprising as
- 2 an active ingredient L-2-oxothiazolidine-4-carboxylate in a concentration ranging from about
- $3 \quad 0.02 \text{ mg/mL} \text{ to about } 0.5 \text{ mg/mL}.$
- 1 Claim 62 (withdrawn): A unit dosage form for the treatment of herpes simplex and conditions
- 2 giving rise thereto, said unit dosage form being a topical dermal dosage form selected from the
- 3 group consisting of topical lotions, gels, creams, and emulsions, comprising as active
- 4 ingredients:
- 5 (a) ascorbic acid,
- 6 (b) 2-amino-2-deoxy-D-glucose,
- 7 (c) zinc sulfate, and
- 8 (d) L-lysine hydrochloride.

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 $\mu$ g/mL to about 2500  $\mu$ g/mL.

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Claim 63 (withdrawn): A unit dosage form in accordance with claim 62 in which the 1 2 concentrations of said active ingredients are as follows: (a) about 1.3  $\mu$ g/mL to about 30  $\mu$ g/mL of ascorbic acid, 3 (b) about 0.01 mg/mL to about 0.2 mg/mL of 2-amino-2-deoxy-D-glucose, 4 (c) about 0.06  $\mu$ g/mL to about 8.5  $\mu$ g/mL of zinc sulfate, and 5 (d) about 1.6  $\mu$ g/mL to about 23  $\mu$ g/mL of L-lysine hydrochloride. 6 Claim 64 (withdrawn): A unit dosage form in accordance with claim 63 further comprising as 1 an active ingredient  $Cu^{+2}$  in a concentration ranging from about 0.15  $\mu$ g/mL to about 15  $\mu$ g/mL. 2 Claim 65 (withdrawn): A unit dosage form in accordance with claim 64 further comprising as 1 an active ingredient quercetin in a concentration ranging from about 0.12  $\mu$ g/mL to about 2.75 2 3  $\mu$ g/mL. Claim 66 (withdrawn): A unit dosage form in accordance with claim 65 further comprising as 1 an active ingredient heparin sodium in a concentration ranging from about 0.6 unit/mL to about 8 2 3 units/mL. 1 Claim 67 (withdrawn): A unit dosage form in accordance with claim 66 further comprising as 2 an active ingredient D, $\alpha$ -tocopherol in a concentration ranging from about 16  $\mu$ g/mL to about 3  $1600 \mu g/mL$ . Claim 68 (withdrawn): A unit dosage form in accordance with claim 67 in which said D, \alpha-1 tocopherol is in the form of D, $\alpha$ -tocopherol nicotinate in a concentration ranging from about 19 2 3  $\mu$ g/mL to about 2600  $\mu$ g/mL. 1 Claim 69 (withdrawn): A unit dosage form in accordance with claim 67 in which said D,α-

tocopherol is in the form of D, $\alpha$ -tocopherol succinate in a concentration ranging from about 19